self-regulatory organization and the Commission.

(B) An applicant or registrant at its option, but not at the option of the lender, may, if the subordination agreement so provides, make a payment at any time of all or any portion of the payment obligation thereunder prior to the scheduled maturity date of such payment obligation (hereinafter referred to as a "special prepayment"). No special prepayment shall be made if, after giving effect thereto (and to all payments of payment obligations under any other subordination agreements then outstanding, the maturity or accelerated maturities of which are scheduled to fall due within six months after the date such special prepayment is to occur pursuant to this provision, or on or prior to the date on which the payment obligation in respect to such special prepayment is scheduled to mature disregarding this provision, whichever date is earlier) without reference to any projected profit or loss of the applicant or registrant, the adjusted net capital of the applicant or registrant is less than the greatest of: *(1)* 10 percent of the following amount: the customer funds required to be segregated pursuant to the Act and these regulations less the market value of commodity options purchased by option customers on or subject to the rules of a contract market, provided, however, the deduction for each option customer shall be limited to the amount of customer funds in such option customer's account; *(2)* for securities brokers or dealers, the amount of net capital specified in Rule 15c3–1d(c)(5)(ii) of the regulations of the Securities and Exchange Commission (17 CFR 240.15c3–1d (c)(5)(ii)); or *(3)* 200 percent of the appropriate minimum dollar amount required by paragraph (a)(1)(i) of this section, nor shall any special prepayment be made if pre-tax losses during the latest three-month period were greater than 15 percent of current excess adjusted net capital. Notwithstanding the above, no prepayment shall occur without the prior written approval of the designated self-regulatory organization and the Commission.

(viii) *Suspended repayment.* (A) The payment obligation of the applicant or registrant in respect of any subordination agreement shall be suspended and shall not mature if, after giving effect to payment of such payment obligation (and to all payments of payment obligations of the applicant or registrant under any other subordination agreement(s) then outstanding which are scheduled to mature on or before such payment obligation), the adjusted net capital of the applicant or registrant would be less than the greatest of: *(1)* 6 percent of the following amount: The customer funds required to be segregated pursuant to the Act and these regulations less the market value of commodity options purchased by option customers on or subject to the rules of a contract market, provided, however, the deduction for each option customer shall be limited to the amount of customer funds in such option customer's account; *(2)* for securities brokers or dealers, the amount of net capital specified in Rule 15c3–1d(b)(8)(i) of the regulations of the Securities and Exchange Commission (17 CFR 240.15c3–1d(b)(8)(i)); or *(3)* 120 percent of the minimum dollar amount required by paragraph (a)(1)(i) of this section: *Provided,* That the subordination agreement may provide that if the payment obligation of the applicant or registrant thereunder does not mature and is suspended as a result of the requirement of this paragraph (h)(2)(viii) for a period of not less than six months, the applicant or registrant shall then commence the rapid and orderly liquidation of its business, but the right of the lender to receive payment, together with accrued interest or compensation, shall remain subordinate as required by the provisions of this section.

* * * * *

(3) * * *

(ii) *Notice of maturity or accelerated maturity.* Every applicant or registrant shall immediately notify the designated self-regulatory organization and the Commission if, after giving effect to all payments of payment obligations under subordination agreements then outstanding which are then due or mature within the following six months without reference to any projected profit or loss of the applicant or registrant, its adjusted net capital would be less than: (A) 120 percent of the minimum dollar amount required by paragraph (a)(1)(i) of this section; (B) 6 percent of the following amount: The customer funds required to be segregated pursuant to the Act and these regulations less the market value of commodity options purchased by option customers on or subject to the rules of a contract market, provided, however, the deduction for each option customer shall be limited to the amount of customer funds in such option customer's account; or (C) For securities brokers or dealers, the amount of net capital specified in Rule 15c3–1d(c)(2) of the regulations of the Securities and Exchange Commission (17 CFR 240.15c3–1d(c)(2)).

* * * * *

(v) *Temporary subordinations.* To enable an applicant or registrant to participate as an underwriter of securities or undertake other extraordinary activities and remain in compliance with the adjusted net capital requirements of this section, an applicant or registrant shall be permitted, on no more than three occasions in any 12-month period, to enter into a subordination agreement on a temporary basis which has a stated term of no more than 45 days from the date the subordination agreement became effective: *Provided,* That this temporary relief shall not apply to any applicant or registrant if the adjusted net capital of the applicant or registrant is less than the greatest of: (A) 7 percent of the following amount: the customer funds required to be segregated pursuant to the Act and these regulations less the market value of commodity options purchased by option customers on or subject to the rules of a contract market, provided, however, the deduction for each option customer shall be limited to the amount of customer funds in such option customer's account; (B) For securities brokers or dealers, the amount of net capital specified in Rule 15c3–1d(c)(5)(i) of the Securities and Exchange Commission (17 CFR 240.15c3–1d(c)(5)(i)); or (C) 120 percent of the appropriate minimum dollar amount required by paragraph (a)(1)(i) of this section; or the amount of equity capital as defined in paragraph (d) of this section is less than the limits specified in paragraph (d) of this section. Such temporary subordination agreement shall be subject to all the other provisions of this section.

* * * * *

Issued in Washington, D.C. on September 15, 1982, by the Commission.

Jane K. Stuckey,

Secretary of the Commission.

[FR Doc. 82–25914 Filed 9–20–82; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 10

[T.D. 82–165]

Generalized System of Preferences; Evidence of the Country of Origin; Correction

AGENCY: Customs Service; Treasury.

ACTION: Final rule; correction.

SUMMARY: This document corrects an error in the effective date of a final rule relating to the Generalized System of Preferences which appeared at page 40160 in the Federal Register of Monday, September 13, 1982 (47 FR 40160).

FOR FURTHER INFORMATION CONTACT: Todd J. Schneider, Regulations Control Branch, U.S. Customs Service (202–566–8237).

The following correction is made to the document:

On page 40160, right-hand column, the date under the caption **EFFECTIVE DATE:** is corrected to read "September 13, 1982, * * *".

Dated: September 15, 1982.

Marvin M. Amernick,

Acting Director, Regulations Control and Disclosure Law Division.

[FR Doc. 82–25998 Filed 9–20–82; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 77N–0143]

Cultured and Acidified Milks, Cultured and Acidified Buttermilks, Yogurts, and Eggnog; Confirmation of Effective Date and Further Amendments; and Stay of Effective Date of Certain Provisions

AGENCY: Food and Drug Administration.

ACTION: Final rule; stay of effective date; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of and further amending certain provisions of the standards of identity for acidified milk, acidified lowfat milk, acidified skim milk, cultured milk, cultured lowfat milk, cultured skim milk, eggnog, yogurt, lowfat yogurt, and nonfat yogurt. FDA also is staying certain provisions of these standards and confirming the redesignation of the standard of identity for skim milk.

DATES: Compliance with the provisions being revised herein may begin November 22, 1982. Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

Objections to the provisions being revised herein by October 21, 1982.

Except as to those provisions stayed or amended, compliance with the January 30, 1981 final rule may have begun March 31, 1981, and all products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF–215), Food and Drug Administration, 200, C St. SW., Washington, DC 20204, 202–245–1155.

SUPPLEMENTARY INFORMATION: A final rule was published in the Federal Register of January 30, 1981 (46 FR 9924), redesignating 21 CFR 131.145 *Skim milk* as 21 CFR 131.143 *Skim milk* and establishing standards of identity for acidified milk (21 CFR 131.111), cultured milk (21 CFR 131.112), acidified lowfat milk (21 CFR 131. 136), cultured lowfat milk (21 CFR 131. 138), acidified skim milk (21 CFR 131.144), cultured skim milk (21 CFR 131.146), eggnog (21 CFR 131.170), yogurt (21 CFR 131.200), lowfat yogurt (21 CFR 131.203), and nonfat yogurt (21 CFR 131. 206). The final rule provided that any person who would be adversely affected could at any time, on or before March 2, 1981, file written objections to the final rule and request a hearing on the specific provisions to which there were objections.

Twenty-one responses were filed objecting to specific provisions of the final rule and in most cases requesting a hearing. Under section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)) (the act), FDA has considered the objections and requests for a hearing and the conclusions are as follows:

Objections and Requests for a Hearing

General

1. *Other Milk-derived Ingredients.* Objectors assert that replacing the phrase "other milk-derived ingredients" in §§ 131.111(e)(1), 131.112(d)(1), 131.136(e)(1), 131.138(d)(1), 131.144(e)(1), 131.146(d)(1), 131.170(e)(1), 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) with a limited list of names of milk-derived ingredients, does not promote honesty and fair dealing in the interest of consumers because this interpretation of the phrase bars the use of other safe, nutritional, and functional milk-derived ingredients. The objectors also assert that exclusion of traditional milk-derived ingredients, e.g., partially delactosed skim milk, partially hydrolyzed whey, partially hydrolyzed skim milk, low sodium milks, casein, and caseinates, does not appear to have any rational factual basis, in light of FDA's past interpretation of the phrase to include many or all of these ingredients. The objections also maintain that a definition of the phrase "other milk-derived ingredients" should be established at a hearing.

FDA believes that the objectors raise a genuine and substantial issue of fact that must be resolved at a public hearing as provided for in 21 CFR 12.24. Therefore, FDA is staying the effective date of the provisions of §§ 131.111(e)(1), 131.112(d)(1), 131.136(e)(1), 131.138(d)(1), 131.144(e)(1), 131.146(d)(1), 131.170(e)(1), 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) that restrict the kinds of safe and suitable milk-derived ingredients that may be used as optional ingredients to increase the nonfat solids contents of these foods, pending the outcome of a public hearing. It should be noted that if no adverse comments are received to the amendment discussed in item 2, below, the paragraphs in all of the yogurt standards will be redesignated, so the paragraphs listed above which are affected by this stay will be changed from § 131.200(c)(1)to § 131.200(d)(1); § 131.203(c)(1) to § 131.203(d)(1); and § 131.206(c)(1) to § 131.206(d)(1).

2. *Optional Addition of Vitamins A and D to Yogurts and Eggnog.* Objectors assert that the standards of identity for eggnog (§ 131.170), yogurt (§ 131.200), lowfat yogurt (§ 131.203), and nonfat yogurt (§ 131.206 (should be amended to provide for the optional addition of vitamins A and D, as the other standards in the final rule do. Reasons given for the amendments are that yogurts are often used as dietary replacements for milk, particularly in the diets of children, and that the requested amendments would be consistent with other milk product standards of identity and would prevent the possibility that a yogurt manufacturer's product would be out of compliance with these standards if the manufacturer uses milk with added vitamins as an ingredient to produce yogurts.

FDA is persuaded that there is merit in permitting the addition of vitamins A and D to yogurt, lowfat yogurt, and nonfat yogurt, but not to eggnog. The agency is aware that children may consume significant amounts of yogurt products, especially flavored yogurts. In addition, many children who cannot tolerate milk physiologically or who dislike milk, are encouraged to consume yogurts and other products. Permitting the addition of vitamins A and D to these products would offer consumers an alternative group of dairy products as

a source of these vitamins. At the same time, the levels being proposed for addition of the vitamins do not provide a significant potential for excess consumption of these nutrients.

It is FDA's current policy to permit the addition of a nutrient to a food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease. FDA only applies the policy where sufficient information is available to identify the nutritional problem and the affected population groups and where the food is suitable to act as a vehicle for the added nutrient. Because no information on eggnog was submitted to support the inclusion of vitamins A and D to eggnog and inasmuch as eggnog is a seasonal product, FDA concludes that eggnog is not a significant vehicle for added vitamins A and D.

Accordingly, FDA is revising §§ 131.200, 131.203, and 131.206, by adding a new paragraph (b), to each of the three standards for yogurts. This change will necessitate redesignating each subsequent paragraph and including labeling provisions in each standard, as set out below. FDA is allowing interested persons until October 21, 1982 to submit written objections to this amendment.

Cultured and Acidified Milks

3. *Color Additives.* Objectors contend that the provisions in §§ 131.111(e)(4), 131.112(d)(4), 131.136(e)(4), 131.138(d)(4), 131.144(e)(4), and 131.146(d)(4) which limit the type of color additives to those that do not impart a color simulating the color of milkfat or butterfat are unreasonable. The objectors maintain that it is common practice to use color additives to assure uniform color in flakes or granules of milkfat and butterfat.

FDA advises that the basis for the color additive limitation may not have been clear in the preamble to the January 30, 1981 final rule because a sentence was inadvertently dropped from the text. The sentence explained that the intent of the limited use of color additives imposed in §§ 131.111(e)(4), 131.112(d)(4), 131.136(e)(4), 131.138(d)(4), 131.144(e)(4), and 131.146(d)(4) is to prohibit the addition of yellow color, directly to the fluid products, in a manner that could give the products the appearance of containing more milkfat than they actually do, thus misleading consumers about the value of the products. The intent, therefore, was not to prohibit the use of color additives in butterfat or milkfat in the form of flakes or granules which may be added to acidified and cultured buttermilks. However, when butterfat or milkfat flakes or granules are used in acidified or cultured buttermilks, all of the ingredients, including color additives, in the flakes or granules must be declared in the ingredient statement. In order to clarify these provisions, FDA is revising §§ 131.111(e)(6), 131.112(d)(6), 131.136(e)(6), 131.138(d)(6), 131.144(e)(6), and 131.146(d)(6) to read "Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules". In light of the foregoing explanation and clarification, FDA believes that the objection does not raise an issue of fact that warrants a hearing.

Eggnog

4. *Minimum Milk Solids Not Fat Requirement.* Objectors assert that a milk solids not fat minimum requirement is not necessary in the standard of identity for eggnog (§ 131.170(a)). The objectors point out that the definition on which this standard is based, found in the "Grade A Pasteurized Milk Ordinance—1965 Recommendations of the U.S. Public Health Service" (PMO), and most State standards for eggnog only require minimum levels of milkfat and egg yolk solids. The objectors further assert that an eggnog containing the minimum 8.25 percent milk solids not fat required by the standard would be too viscous for consumers' tastes.

FDA believes that the objectors raise a genuine and substantial issue of fact that must be resolved at a public hearing as provided for in 21 CFR 12.24. Therefore, FDA is staying the effective date of that portion of § 131.170(a) that sets a minimum milk solids not fat level of 8.25 percent in eggnog, pending the outcome of a public hearing.

5. *Limitation of the Use of Color Additives.* Objectors argue that the limitation established in § 131.170(e)(4) on the use of color additives that simulate the color of egg yolk, butterfat, or milkfat is unreasonable and not in the best interests of consumers. The objectors maintain that States have permitted the use of color additives in eggnog for years and, furthermore, consumers have come to expect a deeper yellow color than could be normally obtained from egg yolks and milkfat alone. One objector asserts that it is fairer to permit manufacturers the use of color additives to give eggnog an improved, uniform appearance year round than it is to create a situation in which highly colored egg yolks obtained from specifically fed laying flocks would be used to color the food, since color from the later source would not be required to be declared on the label of the food.

FDA believes that the objectors raise a genuine and substantial issue of fact that must be resolved at a public hearing as provided for in 21 CFR 12.24. Therefore, FDA is staying the effective date of that portion of § 131.170(e)(4) that prohibits the use of color additives that simulate the color of egg yolk, butterfat, or milkfat, pending the outcome of a public hearing. Until such time as this issue is resolved, the safe and suitable use of color additives that simulate the color of egg yolk, milkfat, or butterfat will not be the basis for regulatory action.

6. *Post-pasteurization Addition of Color Additives and Flavoring Ingredients.* Objectors state that the provision in § 131.170(a) requiring that color additives and, more importantly, flavoring ingredients be added prior to pasteurization of the final product is reasonable and that it will result in less palatable and/or more expensive products. The objectors maintain that eggnog characteristically contains rum flavor, which is volatile, and nutmeg, which becomes lodged in the pasteurization equipment. One of the objectors argues that it is the responsibility of manufacturers, in line with good manufacturing practice, to take the precautionary measures necessary to assure that a safe product reaches the consumer and offers the past record of eggnog as evidence that these measures have been taken. The objectors agree that the egg ingredient should be added prior to pasteurization, and state that this procedure is consistent with good manufacturing practices and would adequately protect consumers against any potential health hazard resulting from use of the egg ingredient.

FDA believes that the objectors have presented sufficient information to justify revising § 131.170(a) to permit addition of color additives and flavoring ingredients after pasteurization or ultra-pasteurization. This is predicated on the fact that these ingredients, as well as the finished food, must be free from physical, chemical, or microbiological contamination as required by the act. FDA is allowing interested persons until October 21, 1982 to submit written objections to this amendment.

Yogurts

7. *Heat-treatment after Culturing.* Objectors state that §§ 131.200(a) and (e)(1)(ii), 131.203(a) and (e)(1)(iii), and 131.206(a) and (e)(1)(ii) (redesignated as §§ 131.200(a) and (f)(1)(ii), 131.203(a) and (f)(1)(iii), 131.206(a) and (f)(1)(ii) in the final rule set forth below), which provide for the heat-treatment of yogurts

after culturing, will confuse and mislead the public into believing that these products have been manufactured in the traditional way. The objectors also contend that the heat-treatment provisions benefit only those processors who operate under less than satisfactory sanitary conditions.

This issue was discussed in the preamble to the final rule published in the **Federal Register** of January 30, 1981 (46 FR 9924). FDA maintains its position that informative labeling, such as the mandatory declaration "heat-treatment after culturing" which must appear on the label of all yogurts that have been heated after culturing, provides sufficient information for consumers to differentiate the traditional product from the heat-treated product. The agency does not agree that use of a post-culturing heat treatment will cover up unsanitary manufacturing conditions and no evidence to support this view was provided. FDA concludes that this objection does not raise an issue of fact that warrants a hearing.

8. *"Heat-treated After Culturing" Labeling.* (a) One objector asserts that the required labeling in §§ 131.200(e)(1)(ii), 131.203(e)(1)(iii), and 131.206(e)(1)(ii) (redesignated as §§ 131.200(f)(1)(ii), 131.203(f)(1)(iii), and 131.206(f)(1)(ii) in the final rule set forth below) is unnecessary when yogurts are heat-treated only enough to destroy part of the total microbial population. Under such circumstances, the shelf life of the product is extended and the microbial population often regenerates to preexisting levels by the time the yogurt is purchased. The objector maintains that consumers will be misled into thinking that all of the microorganisms have been destroyed whenever they see the phrase on a label.

FDA does not agree and reiterates its position that product labeling must be factual and that any heat-treatment applied to yogurt after the food is cultured triggers the "heat-treated after culturing" labeling requirement, regardless of the extent of bacterial destruction. This issue was discussed in the preamble to the final rule published in the **Federal Register** of January 30, 1981 (46 FR 9924). FDA explained that the purpose of the phrase is to alert consumers to the fact that the traditional food has been subjected to heat treatment which may have caused changes such as partial or complete reduction in the number of characterizing microorganisms or changes in enzyme content, aroma, or flavor. The objector does not suggest any alternative labeling that would inform consumers of these changes. FDA concludes that this objection does not raise an issue of fact that warrants a hearing.

(b) One objector also asserts that it is unnecessary to include the "heat-treated after culturing" labeling as part of the name of a yogurt when that yogurt is used as an ingredient in another food. The objector interprets the standards to mean that the phrase must accompany the names of heat-treated yogurts when they are used as ingredients in other foods.

FDA advises the objector that his interpretation is incorrect and that the "heat-treated after culturing" phrase need not appear in a label statement of ingredients when a heat-treated yogurt is used as an ingredient in another food. FDA concludes that this objection does not raise an issue of fact that warrants a hearing.

9. *Milkfat Minimum in "Yogurt".* An objector states that the 3.25 percent minimum milkfat requirement in § 131.200(a) should apply only when the optional dairy ingredients provided for in paragraph (b) of § 131.200 (redesignated as § 131.200(c) in the final rule set forth below) are used to meet the minimum fat (3.25 percent) and minimum milk solids not fat (8.25 percent) requirements for yogurt. The objector states that the language in paragraph (a) of § 131.200 implies that the milkfat minimum must be met after any addition of other optional ingredients to increase the milk solids not fat content of yogurt above the minimum requirement. The objector maintains that applying the milkfat minimum to yogurt which has been made to contain milk solids not fat at a level higher than the minimum requirement of the standard will discourage manufacturers from using higher levels of milk solids not fat in yogurt because such addition would then require the use of more milkfat. The objector wants § 131.200(a) amended so that the minimum milkfat requirement only applies to the optional dairy ingredients utilized in accordance with paragraph (b) of § 131.200 (redesignated as § 131.200(c) in the final rule set forth below).

FDA agrees that § 131.200(a) requires that the milkfat minimum of 3.25 percent must be met after any addition of other optional ingredients. (FDA points out, however, that § 131.200(a) also provides that the minimum 3.25 percent milkfat and 8.25 percent milk solids not fat requirement applies prior to the addition of any bulky flavors.) While paragraph (a) of § 131.200 provides for the use of other optional dairy ingredients to increase the milk solids not fat content of the yogurt ingredients to 8.25 percent or above, it was never intended to provide and does not provide for a proportionate decrease in the minimum milkfat content of yogurt.

FDA believes that the objector has raised a genuine and material issue of fact that must be resolved at a hearing as provided for in 21 CFR 12.24. The hearing issue will be: "Whether the minimum milkfat requirement of 3.25 percent in 21 CFR 131.200(a) should apply to yogurt before or after the addition of one or more of the optional sources of milk solids not fat listed in paragraph (c)(1) of that section." Therefore, FDA is staying the effective date of the requirement in § 131.200(a) that is the subject of the hearing issue.

10. *Fresh Fluid Dairy Ingredients as the Basic Ingredients Versus Use of Condensed and Dry Dairy Ingredients Reconstituted with Water.* (a) An objector states that the standards of identity for yogurt (§ 131.200), lowfat yogurt (§ 131.203), and nonfat yogurt (§ 131.206) should be modified to provide for the manufacture of yogurts from condensed or dry dairy ingredients reconstituted with water. The objector maintains that yogurt manufacturers in Florida and the Southeastern States will be adversely affected because the fluid milk supplies in these States are often insufficient for use in yogurt manufacture. If reconstituted dairy ingredients are not permitted, the price of yogurts will be artificially and unnecessarily inflated in those areas.

FDA believes that the objector raises a genuine and substantial issue of fact that must be resolved at a public hearing as provided for in 21 CFR 12.24. Therefore, FDA is staying the effective date of those portions of §§ 131.200(a), 131.203(a), and 131.206(a) that exclude the use of reconstituted dairy ingredients as the basic ingredients in the manufacture of yogurts, pending the outcome of a public hearing. Until such time as this issue is resolved, the use of reconstituted dairy ingredients as the basic ingredients in the manufacture of yogurt, lowfat yogurt, or nonfat yogurt will not be the basis for regulatory action.

(b) The objector believes that it would allow maximum flexibility in product formulation if skim milk or skim milk reconstituted from concentrated and dry skim milk were included in the list of dairy ingredients in § 131.200(c)(1) (redesignated as § 131.200(d)(1) in the final rule set forth below) that may be used to increase the nonfat solids content of yogurt.

FDA believes it is impossible to increase the milk solids not fat content

of yogurt above 8.25 percent by using either skim milk or reconstituted skim milk. These ingredients contain approximately 9 percent milk solids not fat and 91 percent water. While the addition of skim milk or reconstituted skim milk would contribute milk solids not fat, there would be a concomitant decrease in the percent of milkfat in the dairy ingredients combined to produce yogurt due to the increased volume of water contributed by the skim milk or reconstituted skim milk. The objector did not submit any data or information demonstrating that skim milk or reconstituted skim milk can be used to increase the milk solids not fat content of yogurt above the 8.25 percent minimum without also decreasing the milkfat content below the 3.25 percent minimum. FDA concludes that these ingredients are inappropriate dairy ingredients for increasing the milk solids not fat content of yogurt and that this objection does not raise an issue of fact that warrants a hearing.

11. *Preservatives.* Objectors assert that the standards of identity for yogurt (§ 131.200(c)), lowfat yogurt (§ 131.203(c)), and nonfat yogurt (§ 131.206(c)) (redesignated as §§ 131.200(d), 131.203(d), and 131.206(d) in the final rule set forth below) should provide for the use of preservatives such as potassium sorbate and sorbic acid, to prohibit the growth of yeasts and molds and extend the shelf life of the foods 15 to 30 days. The objectors maintain that the use of preservatives is economically beneficial to consumers.

FDA believes that the objectors raised a genuine and substantial issue of fact that must be resolved at a public hearing as provided for in 21 CFR 12.24. Therefore, FDA is staying the effective date of those portions of §§ 131.200(d), 131.203(d), and 131.206(d) insofar as they exclude the addition of preservatives to yogurts, pending the outcome of a public hearing. Until such time as this issue is resolved, the appropriate use of preservatives in these foods will not be the basis for regulatory action.

12. *"Sweetened" Labeling.* One objector states that the required label declaration "sweetened" in §§ 131.200(e)(1)(i), 131.203(e)(1)(ii), and 131.206(e)(1)(i) (redesignated as §§ 131.200(f)(1)(i), 131.203(f)(1)(ii), and 131.206(f)(1)(i) in the final rule set forth below) is not justifiable for plain yogurts that only contain sufficient sweetener to soften the tart flavor of the acid, but not enough to characterize the yogurts as sweet. The objector maintains that consumers will be misled into thinking the product will taste sweet or will be high in calories due to the word "sweetened" on the label as part of the name of the food.

It is the agency's position that yogurt is sweetened when a nutritive carbohydrate sweetener is added, either to lessen the tartness of the food or to create a perceptible sweet taste, and that consumers should so be informed in a straightforward manner. The most effective method of informing the consumer that sugar or some other sweetener has been added to the food, is to require the word "sweetened" as part of the name of the food, thereby clearly differentiating sweetened from plain yogurt. Therefore, FDA concludes that these objections do not raise an issue of fact that warrants a hearing.

13. *Post-pasteurization Addition of Flavors.* An objector argues that the provisions of the standards of identity for yogurts, §§ 131.200(a), 131.203(a), and 131.206(a), that permit the addition of bulky flavors after yogurts have been pasteurized also should apply to nonbulky flavors such as lemon, vanilla, and coffee. The objector maintains that some of the chemical components of these flavors volatilize upon heating and that other components may be altered by heating in such a way that bitterness or other unpleasant tastes are created. In either case, the flavor of the final product would be adversely affected.

FDA believes that valid technological reasons have been provided by the objector for permitting the addition of nonbulky flavors to yogurt, lowfat yogurt, and nonfat yogurt, after pasteurization. Therefore, FDA is revising §§ 131.200(a), 131.203(a), and 131.206(a) by removing the words "and bulky flavoring material" from the sentence that now reads "The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture and bulky flavoring material", and adding the sentence "Flavoring ingredients may be added after pasteurization or ultra-pasteurization". It is the responsibility of the manufacturers of yogurts to assure that the addition of any ingredients after pasteurization will not microbiologically contaminate the final product. FDA is allowing interested persons until October 21, 1982 to submit written objections to this amendment.

14. *Minimum Titratable Acidity.* An objector contends that the minimum titratable acidity of 0.9 percent, expressed as lactic acid, as required for yogurts in §§ 131.200(a), 131.203(a), and 131.206(a), is too high for some consumers' tastes and that 0.75 percent is the common industry practice.

FDA believes that the objector raises a genuine and substantial issue of fact that must be resolved at a public hearing as provided for in 21 CFR 12.24. Therefore, FDA is staying those portions of §§ 131.200(a), 131.203(a), and 131.206(a) that set a minimum titratable acidity of 0.9 percent, expressed as lactic acid, pending the outcome of a public hearing. Until such time as this issue is resolved, yogurt, lowfat yogurt, or nonfat yogurt will not be required to meet the 0.9 percent minimum level of titratable acidity.

Objections Without Requests for a Hearing

Cultured and Acidified Milks

15. *Optional Acidifiers.* An objector asserts that the omission of acetic acid from the list of optional acidifiers that may be used in acidified milk (§ 131.111(d)), acidified lowfat milk (§ 131.136(d)), and acidified skim milk (§ 131.144(d)) is unjustifiable. The objector maintains that acetic acid is an integral component of the flavor of buttermilk, so it is reasonable to add the acid to the list of other acids that may be used to make acidified versions of buttermilk.

FDA agrees and is adding acetic acid to the lists of optional acidifying ingredients in §§ 131.111(d), 131.136(d), and 131.144(d) and is allowing interested persons until October 21, 1982 to submit written objections to this amendment.

16. *Minimum Milkfat Requirement for "Cultured Buttermilk".* An objector argues that the minimum milkfat requirement of 3.25 percent for "cultured buttermilk" (§ 131.112(a)) would cause the objector to increase the milkfat content of its "cultured buttermilk" or be required to change the name of its product to "Lowfat cultured buttermilk". The objector's view is that its product, which it calls "cultured buttermilk", was patterned after the composition of buttermilk obtained from the manufacture of butter from cream.

FDA advises that while some firms may have utilized the name "cultured buttermilk" for a product containing 0.5 to 2 percent milkfat, there are many who use a higher milkfat content. For the purpose of uniformity in composition and labeling within product groups and between products it is essential that names and composition be standardized wherever possible. It is the view of FDA that this promotes honesty and fair dealing in the interest of consumers.

Yogurts

17. *Percent Milkfat Declaration on Lowfat Yogurt Labels.* Objectors assert, in opposition to the label requirements of § 131.203(e)(1)(i) (redesignated as

§ 131.203(f)(1)(i) in the final rule set forth below), that a declaration of the actual quantity of fat, as is found in nutrition labeling, is more informative and less misleading than a declaration of the percent milkfat in the name of the food.

The purpose of requiring the declaration of the percent fat in the name of the food is to provide the consumer with information, at the time of purchase, about the fat content (to the nearest 0.5 percent) of the lowfat yogurt being purchased. The practice is reasonable because the standard of identity for lowfat yogurt provides for a milkfat content of from 0.5 to 2.0 percent. While nutrition labeling requires more definitive information, such as the grams of fat per serving, the nutrition labeling of lowfat yogurt is only required by virtue of the fact that the proposed standard of identity for lowfat yogurt would require the percentage of milkfat to be declared in the name of the food.

18. *Alternative Spelling for Yogurt.* An objector states that the mandatory name of the food "Yogurt", as required in §§ 131.200, 131.203, and 131.206, prevents the use of the name "yogourt". Therefore, the interested party requests that the alternate spelling of the name be provided for in the standards. The request for such consideration is based on the fact that the interested party has been marketing these foods under the name "yogourt" since the mid 1940's.

This issue was discussed in the preamble of the final rule published in the Federal Register of January 30, 1981 (46 FR 9924) where it was explained that the word "yogourt" may be used as a fanciful name by those who have rights to such name, but it must be accompanied by the standardized name of the food "yogurt".

19. *"Heat-treated after culturing" Labeling.* An objector interprets the standards to mean that the "heat-treated after culturing" phrase shall accompany the names of the dairy ingredients in the label statement of ingredients rather than accompanying the name of the food on the principal display panel. This objector maintains that the phrase does not convey any valuable information to consumers.

FDA advises that the objectors's interpretation is incorrect and that the "heat-treated after culturing" phrase must accompany the name of the food wherever it appears on the principal display panel or panels of the label, e.g., "nonfat yogurt (heat-treated after culturing)". The phrase need not accompany the name(s) of the dairy ingredients in the label statement of ingredients of the food. FDA also disagrees with the objector's contention that the phrase does not convey any valuable information to consumers. As discussed in the preamble of the final rule published in the Federal Register of January 30, 1981 (46 FR 9924), many consumers approve of requiring the "heat-treated after culturing" labeling as part of the name of the food so they can avoid purchasing heat-treated yogurts.

Provisions stayed. Under section 701(e) of the act, FDA hereby announces that the effective date of the following provisions of the January 30, 1981 final rule is stayed by the filed objections, pending a public hearing to be announced at a later date:

1. Those provisions of §§ 131.111(e)(1), 131.112(d)(1), 131.136(e)(1), 131.138(d)(1), 131.144(e)(1), 131.146(d)(1), 131.170(e)(1), 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) that restrict the type of milk-derived ingredients that may be used, to those so named, to increase the nonfat solids content of cultured and acidified milks, eggnog, and yogurts;

2. That portion of § 131.170(a) that sets a minimum milk solids not fat requirements of 8.25 percent in eggnog;

3. That portion of § 131.170(e)(4) that prohibits the use of color additives that simulate the color of egg yolk, butterfat, or milkfat;

4. Those portions of §§ 131.200(a), 131.203(a), and 131.206(a) that exclude the use of reconstituted dairy ingredients as the basic ingredient in the manufacture of yogurts;

5. Those portions of §§ 131.200(c), 131.203(c), and 131.206(c) insofar as they exclude the addition of preservatives to yogurts; and,

6. Those portions of §§ 131.200(a), 131.203(a), and 131.206(a) that set a minimum titratable acidity of 0.9 percent, expressed as lactic acid.

7. The requirement in § 131.200(a) that the 3.25 percent minimum milkfat level applies to yogurt after the addition of one or more of the optional sources of milk solids not fat listed in § 131.200(c)(1).

List of Subjects in 21 CFR Part 131

Cream, Food standards, Milk, Yogurt.

PART 131—MILK AND CREAM

Therefore, under the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 131 is amended as follows:

1. In § 131.111 by revising paragraphs (d) and (e)(6) to read as follows:

§ 131.111 Acidified milk.

* * * * *

(d) *Optional acidifying ingredients.* Acetic acid, adipic acid, citric acid, fumaric acid, glucono-*delta*-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) * * *

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

* * * * *

2. In § 131.112 by revising paragraph (d)(6) to read as follows:

§ 131.112 Cultured milk.

* * * * *

(d) * * *

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

* * * * *

3. In § 131.136 by revising paragraphs (d) and (e)(6) to read as follows:

§ 131.136 Acidified lowfat milk.

* * * * *

(d) *Optional acidifying ingredients.* Acetic acid, adipic acid, citric acid, fumaric acid, glucono-*delta*-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) * * *

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

* * * * *

4. In § 131.138 by revising paragraph (d)(6) to read as follows:

§ 131.138 Cultured lowfat milk.

* * * * *

(d) * * *

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

* * * * *

5. In § 131.144 by revising paragraphs (d) and (e)(6) to read as follows:

§ 131.144 Acidified skim milk.

* * * * *

(d) *Optional acidifying ingredients.* Acetic acid, adipic acid, citric acid, fumaric acid, glucono-*delta*-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) * * *

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

* * * * *

6. In § 131.146 by revising paragraph (d)(6) to read as follows:

§ 131.146 Cultured skim milk.

* * * * *

(d) * * *

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

* * * * *

7. In § 131.170 by revising paragraph (a) to read as follows:

§ 131.170 Eggnog.

(a) *Description.* Eggnog is the food containing one or more of the optional dairy ingredients specified in paragraph (b), one or more of the optional egg yolk-containing ingredients specified in paragraph (c) of this section, and one or more of the optional nutritive carbohydrate sweeteners specified in paragraph (d) of this section. One or more of the optional ingredients specified in paragraph (e) of this section may also be added. All ingredients used are safe and suitable. Eggnog contains not less than 6 percent milkfat and not less than 8.25 percent milk solids not fat. The egg yolk solids content is not less than 1 percent by weight of the finished food. The food shall be pasteurized of ultra-pasteurized and may be homogenized. Flavoring ingredients and color additives may be added after the food is pasteurized or ultra-pasteurized.

* * * * *

8. In § 131.200 by revising paragraph (a), by redesignating paragraphs (b) through (f) as (c) through (g), and by adding new paragraphs (b) and (f)(1)(iii) to read as follows:

§ 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) *Optional dairy ingredients.* * * *

(d) *Other optional ingredients.* * * *

(e) *Methods of analysis.* * * *

(f) *Nomenclature.* * * *

(1) * * *

(iii) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit".

* * * * *

(g) *Label declaration.* * * *

9. In § 131.203 by revising paragraph (a), by redesignating paragraphs (b) through (f) as (c) through (g), and by adding new paragraphs (b) and (f)(1)(iv) to read as follows:

§ 131.203 Lowfat yogurt.

(a) *Description.* Lowfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Lowfat yogurt, before the addition of bulky flavors, contains not less than 0.5 percent nor more than 2 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, lowfat yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) *Optional dairy ingredients.* * * *

(d) *Other optional ingredients.* * * *

(e) *Methods of analysis.* * * *

(f) *Nomenclature.* * * *

(1) * * *

(iv) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit".

* * * * *

(g) *Label declaration.* * * *

10. In § 131.206 by revising paragraph (a), by redesignating paragraphs (b) through (f) as (c) through (g), and by adding new paragraphs (b) and (f)(1)(iii) to read as follows:

§ 131.206 Nonfat yogurt.

(a) *Description.* Nonfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Nonfat yogurt, before the addition of bulky flavors, contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, nonfat yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946

milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* * * *

(d) *Other optional ingredients.* * * *

(e) *Methods of analysis.* * * *

(f) *Nomenclature.* * *

(1) * * *

(iii) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit".

* * * * *

(g) *Label declaration.* * * *

Any person who will be adversely affected by the foregoing amendments to the final regulation, published in the January 30, 1981 Federal Register (46 FR 9924), may at any time on or before October 21, 1982, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to the amendment that may be stayed by the filing of proper objections, compliance with these amendments to the final regulations may begin November 22, 1982. The mandatory compliance date for the provisions that are revised in this document shall be July 1, 1985. Notice of the filing of objections or lack thereof will be published in the Federal Register. Accordingly, except as to those provisions being herein amended and the provisions listed above as stayed, the effective date of §§ 131.111, 131.112, 131.136, 131.138, 131.143, 131.144, 131.148, 131.170, 131.200, 131.203, and 131.206 as published in the Federal Register of January 30, 1981 (46 FR 9924) is confirmed as follows: Compliance with this regulation, including any required labeling changes, may have begun on March 31, 1981 and all affected products initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: September 14, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-25781 Filed 9-20-82; 8:45 am]

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21 CFR Part 135

[Docket No. 79P-0441]

Frozen Desserts; Standards of Identity for Goat's Milk Ice Cream, Goat's Milk Frozen Custard, and Goat's Milk Ice Milk

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing standards of identity for goat's milk ice cream, goat's milk frozen custard, and goat's milk ice milk by cross-reference to the standards of identity for ice cream and frozen custard and for ice milk. This action will provide for the manufacture of ice cream, frozen custard, and ice milk from goat's milk, which consumers may use as alternatives to products made from cow's milk.

DATES: Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may begin November 22, 1982; objections by October 21, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 8, 1981 (46 FR 60007), FDA published a proposal to establish standards of identity for goat's milk ice cream and goat's milk frozen custard (21 CFR 135.115) and goat's milk ice milk (21 CFR 135.125) cross-referenced to the standards of identity for ice cream and frozen custard (21 CFR 135.110) and ice milk (21 CFR 135.120), respectively. The proposal allowed for the filing of comments by February 8, 1982.

Five comments were received in response to the proposal. The comments and the agency's response are discussed below.

1. Several comments requested that the concentrated and dry forms of goat's milk and goat's cream also be permitted in addition to the liquid form.

FDA advises that any of the dairy ingredients permitted in § 135.115(b) may be used in liquid, concentrated, or dry form. To clarify this issue, FDA is revising § 135.115(b) to read "The optional dairy ingredients referred to in paragraph (a) of this section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form."

2. One comment suggested that goat's milk-derived ingredients, such as whey, caseinates, and coprecipitates of goat's milk protein, be added to the list of optional dairy ingredients that may be used. The comment stated that these ingredients are not now available, but providing for their use now will eliminate the need for amendments at a later date when the ingredients do become available.

FDA cannot approve the use of ingredients before they are actually developed because there are no data with which to establish whether they are safe and suitable. As new goat's milk-derived ingredients are developed and demonstrated to be suitable ingredients, interested persons may submit petitions to amend the standards of identity to provide for their use.

3. One comment suggested that the name of the food be changed from "goat's milk ice cream" to "goat ice cream" because inclusion of the word "milk" may mislead consumers about the nature of the product. The comment also stated that the proper designation should be "goat milk" rather than "goat's milk".

FDA believes the name "goat ice cream" is potentially more confusing than the name "goat's milk ice cream" and, therefore, is not making the suggested change. It is not clear to the agency how inclusion of the word "milk" in the name of the food could mislead consumers since the food is made from goat's milk and/or components of goat's milk. FDA also rejects the suggestion that "goat's milk" be referred to as "goat milk" instead, because the possessive form is the commonly recognized mode of